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David J. Levy Ph.D, Patent Counsel  
GlaxoSmithKline  
Corporate Intellectual Property Dept.  
Five Moore Drive, PO Box 13398  
Research Triangle Park NC 27709-3398

In Re: Patent Term Extension  
Application for  
U.S. Patent No. 5,565,467

MAILED

JAN 22 2007

CENTRAL REEXAMINATION UNIT

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 5,565,467, which claims the human drug product Dutasteride, is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 766 days.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Director will issue a certificate of extension, under seal, for a period of 766 days.

The period of extension, if calculated using the Food and Drug Administration determination of the length of the regulatory review period published in the Federal Register of June 14, 2006, (71 Fed. Reg. 34374), would be 1,099 days. Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (2,038 - 510) + 335 \\ &= 1,099 \text{ days (3.0 years)}\end{aligned}$$

Since the regulatory review period began May 25, 1995, before the patent issued (October 15, 1996), only that portion of the regulatory review period occurring after the date the patent issued has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). (From May 25, 1995, to and including, October 15, 1996, is 510 days; this period is subtracted for the number of days occurring in the testing phase according to the FDA determination of the length of the regulatory review period). No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

However, the 14 year exception of 35 U.S.C. § 156(c)(3) operates to limit the term of the extension in the present situation because it provides that the period remaining in the term of the patent measured from the date of approval of the approved product plus any patent term extension cannot exceed fourteen years. The period of extension calculated above, 1,099 days, would extend the patent from October 15, 2013 to October 18, 2016, which is beyond the 14-year limit (the approval date is November 20, 2001, thus the 14 year limit is November 20, 2015). The period of extension is thus limited to 766 days, by operation of 35 U.S.C. § 156(c)(3). Accordingly, the period of extension is the number of days to extend the term of the patent from its original expiration date, October 15, 2013, to and including November 20, 2015, or 766 days.

The limitations of 35 U.S.C. 156(g)(6) do not operate to further reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.:	5,565,467
Granted:	October 15, 1996

Original Expiration Date<sup>1</sup>: October 15, 2013  
Applicant: Kenneth W. Batchelor, et al.  
Owner of Record: Glaxo, Inc.<sup>2</sup>  
Title: Androsthenone Derivative  
Product Name: Dutasteride soft gelatin capsules<sup>3</sup>  
Term Extended: 766 days  
Expiration Date of Extension: November 20, 2015

Any correspondence with respect to this matter should be addressed as follows:

By mail: Mail Stop Hatch-Waxman PTE  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450.

By FAX: (571) 273-7755

Telephone inquiries related to this determination should be directed to the undersigned at (571) 272-7755.



Mary C. Till  
Legal Advisor  
Office of Patent Legal Administration  
Office of the Deputy Commissioner  
for Patent Examination Policy

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<sup>1</sup>Subject to the provisions of 35 U.S.C. § 41(b).

<sup>2</sup>In the original patent term extension application filing, applicants provided chain of title, name change and merger documents reflecting that the current owner of U.S. Patent No. 5,565,467 as GlaxoSmithKline. Upon review of the USPTO assignment database, the only listed assignment is to Glaxo, Inc. Unless the documents evidencing the current ownership are recorded in the USPTO assignment database, the certificate of extension will issue to Glaxo, Inc.

<sup>3</sup> In the original patent term extension application materials, the approved product is solely referred to as "dutasteride,"referring to dutasteride soft gelatin capsules. Based on information from the FDA electronic Orange Book, however, it appears that the tradename that corresponds to dutasteride soft gelatin capsules is AVODART®. Should the patent term extension applicant require that the certificate of extension issue with the tradename AVODART® as the approved product, then a supplement to the originally filed patent term extension application must be submitted evidencing that the approved product is AVODART® (dutasteride soft gelatin capsules).

cc: Office of Regulatory Policy  
HFD - 7  
5600 Fishers Lane (Rockwall II Rm. 1101)  
Rockville, MD 20857

RE: Dutrasteride  
FDA Docket No.: 2002E-0100

Attention: Beverly Friedman